August 8, 2002

Health Industry Business Communications Council

HIBCC

Dockets Management Branch
Food and Drug Administration
(HFA-305)
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0204

The Health Industry Business Communications Council (HIBCC) is a non-profit standards-development organization, established in 1983 by major national healthcare associations to develop and maintain information technology standards for healthcare applications. HIBCC and the HIBC Standards are accredited by the American National Standards Institute (ANSI) and the European Committee for Standardization (CEN).

In response to the FDA's request for comment on "Bar Code Label Requirements for Human Drug Products" (Docket no. 02N-0204) HIBCC has prepared the following statement:

> HIBCC cannot proffer an opinion on whether or not the FDA should issue a regulation regarding automatic identification of medical products.
>
> If the FDA should decide to support the concept of unique machine-readable item identification for medical products, then HIBCC recommends that the FDA specify the use of the Universal Product Number (UPN) System which embraces both approved industry standards, HIBC and UCC.EAN, for medical products. The National Drug Code, NDC, is considered an intrinsic component of the UPN System.
>
> The current HIBC Supplier Labeling and Provider Application Standards have been attached as reference.

HIBCC has prepared the following comments to the specific questions posed by the FDA in the above referenced docket:

A. General Questions Related to Drugs and Biologics:

2. What information should be contained in the bar code? What do you consider to be critical bar code information that will reduce medical product errors? If data exists, please provide it for the record. What information would be helpful but not necessarily critical, for reducing medication errors? Provide data.

2525 E Arizona Biltmore Circle, Suite 127 ¨ Phoenix, Arizona ¨ 85016
602.381.1091 Voice ¨ 602.381.1093 Fax ¨ info@ hibcc.org ¨ www.hibcc.org

Based on input from both HIBCC-member Suppliers (Manufacturers) and Providers (Hospitals), the HIBC Supplier Labeling Standard provides a structure to identify the product, lot, batch, or serial number, and expiration date. All three data elements are considered important to healthcare providers for accurate identification and traceability of products.

3. Considering current scanners and their ability to read certain symbologies, should the rule adopt a specific bar code symbology (e.g., reduced space symbology (RSS) and 2-dimensional symbology)? Should we adopt one symbology over another, or should we allow for "machine readable" formats? What are the pros and cons of each approach?

HIBCC believes that the FDA should not identify the specific symbology. The information (data elements) contained in the bar code are the critical consideration in determining how auto-identification technology can best assist in the reduction of medical errors, not how the message is "carried" or represented. By not specifying the "carrier" or symbology to be used, the industry can more readily adapt as technology evolves.

4. Assuming that we require bar codes on all human drug products, where on the package should the bar codes be placed? Are there benefits to placing bar codes on immediate containers, such as the bottles, tubes, foiled-wrapped tablets, and capsules, found inside prescription or OTC product cartons? Is there a way to distinguish whether certain containers with a bar code will have a more significant effect on preventing errors than others?

The UPN System provides for a package level indicator. The location of the bar code should be determined by the space available and the utility of the package.

The obvious advantage to placing bar codes on unit-of-use packages is that accurate identification can be made at the point-of-care, where most errors occur, thus reducing the opportunity for human error and system failure.

5. What products already contain bar codes? Who (i.e., hospital, nursing homes, outpatient clinics, retail pharmacies, etc.) uses these bar codes and how? As with all comments, if data exists, please provide it for the record.

It is estimated that approximately 75% of all medical products are currently bar coded. The growing need to build efficiency and cost containment measures into the healthcare system, as well as to secure the integrity of patient care, will necessitate wider application of auto-identification technologies.

2525 E Arizona Biltmore Circle, Suite 127 ¨ Phoenix, Arizona ¨ 85016
602.381.1091 Voice ¨ 602.381.1093 Fax ¨ info@ hibcc.org ¨ www.hibcc.org

The HIBC Provider Application Standard is an accredited standard and provides a system of specifically assigned bar code data messages for identification and tracking of patients, clinicians, procedures, locations and specimens, in clinical settings such as hospitals, nursing homes and clinics.

The use of bar code technology in clinical environments enables identification of key process elements (patient, product, and clinician) providing fast, accurate data capture into a medication management and administration system (MMAS) and further integration into the hospital's clinical information systems. This allows auto-identification technology to be brought forward in the process to the point-of-care, verifying data input and making quality and safety checks on the products and processes being administered.

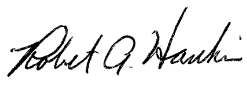
B. Medical Device Questions

1. Should medical devices carry a bar code? What information should be included in the bar code? For example, unlike drug products, medical devices do not have unique identifier numbers.

Medical devices are uniquely identified by the UPN number. This is the numbering system developed by the U.S. Department of Defense and is used by the DOD, Veterans Administration and many group-purchasing organizations such as Premier, Novation, Consorta, and AmeriNet.

Thank you for the opportunity to reply to your request for comments on the Food and Drug Administration's approach to auto-identification of medical products. HIBCC looks forward to continuing to work with the FDA and the industry on this important public safety issue.

Sincerely,



Robert A. Hankin, Ph.D
President & CEO

2525 E Arizona Biltmore Circle, Suite 127 ¨ Phoenix, Arizona ¨ 85016
602.381.1091 Voice ¨ 602.381.1093 Fax ¨ info@ hibcc.org ¨ www.hibcc.org